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[Abbas, Muhammad Zaheer](#)

(2018)

'Potential Role of IP Law & Policy in Achieving Global Health Goals'. In *International Conference on Sustainable Development*, 2018-09-26 - 2018-09-28, New York, United States, USA. (Unpublished)

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Potential Role of IP Law & Policy in Achieving Global Health Goals

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Background

Right to health is globally recognized as a basic **human right**. Both drug “**innovation**” and “**access**” are crucial for achieving the **2030 Agenda’s** goal of improving the health and well-being of all people at all ages (SDG3). Good health is also a prerequisite for achieving some other SDGs like “**eradication of poverty and hunger**” (SDG1&2). There is a two-way relationship between poverty and ill health as **poverty contributes to disease while disease also contributes to poverty**. The current innovation system has problems which lead to both “**innovation**” and “**access**” failures in the pharma sector. This study highlights one of these problems: Evergreening of drug patents.

access to
INNOVATION

Evergreening of Drug Patents

Brand name pharmaceutical companies use different risk-averse and less-costly **evergreening tactics** to extend their exclusive rights beyond 20 years patent term without making any genuine contribution to the progress of science and technology. These tactics include seeking patents for:

- new formulations;
- new combinations;
- new use of a known drug;
- new dosage forms.



Evergreening of drug patents has a two-fold negative impact.

- **Innovation Failures:** Drug companies divert their attention to incremental innovations. The National Institute of Health Care Management (**NIHCM**) found that only **15%** of new drugs are highly innovative.
- **Access Failures:** High cost of drugs because of delayed generic competition.

Patent Litigation

Patent litigation is not a practically viable option to fix the problem of evergreening because:

- Patent litigation is notoriously **risky, costly, lengthy, and cumbersome**.
- The **presumption of validity** of granted patents favors the patentee in litigation.



Approach at International Level

- Instead of allowing powerful countries to dictate TRIPS plus IP standards through **FTAs**, developing countries need to collectively press for reinvigorating **multilateral forums** like the WTO & WIPO. FTAs are pro-profit and pro-evergreening. **Art. 18.37(2)** of the **TPP** specifically protects evergreening.
- The global community needs to honor the commitment to **health as a basic human right** and needs to collectively address drug access and innovation failures.



Research Questions

To what extent can the current innovation system help in achieving the **UN’s 2030 Agenda’s Global Health Goals**? How the practice of “**Evergreening** of drug patents” leads to “**innovation**” and “**access**” failures in the pharma sector? What **policy options** are available at the national level to curtail evergreening? What steps can be taken at the **international level** to harmonize innovation policy in the pharma sector with the UN’s health-related SDGs?

Methodology

This study uses **literature review** and **qualitative empirical** research methods.

Evergreening and SDGs 1,2&3

Access failures caused by evergreening of drug patents have serious implications for **SDGs 1,2&3**. **85%** of the world’s population lives in **low** and **middle-income** countries. **90%** of the population in these countries makes **out-of-pocket** payments for drugs. Ill health in these countries leads to **poverty and hunger**.

Evergreening is a killer even in the US

Alec, a diabetes patient in the **US**, turned 26 on May 20, 2018 and **aged off** his mother’s **insurance** plan. Now, **Insulin** supplies would cost him **\$1300** a month. He **died** in less than one month. Insulin was discovered in **1921**. Evergreening has still kept **cheaper generic** versions of Insulin out of the market.



India’s Unique Approach

India combined two distinct TRIPS flexibilities to curtail evergreening of drug patents.

- India used TRIPS flexibility (under **Art.27.1**) to define **patentability criteria** and raised the **threshold standard** for patentability u/s 3(d) of the Patents Act.
- India used another TRIPS flexibility (under **Art.41.2**) and provided both **pre-grant** and **post-grant** patent opposition procedure to afford third parties an opportunity to challenge the validity of patents within the Patent Office in an **affordable, feasible, and time-efficient** manner.
- India **linked s 3(d)** with its **opposition model**. In India, in **87%** cases, drug patents are opposed **u/s 25(1)(f)**: “not an invention within the meaning of this Act”. It invokes applicability of s 3(d) which provides a notable exception to patentability in India.



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